



JKW

PATENT  
1599-0257P

IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant: Ae-Ri KIM et al. Conf.: 7563  
Appl. No.: 10/782,951 Group: UNKNOWN  
Filed: February 23, 2004 Examiner: UNKNOWN  
For: ORALLY ADMINISTABLE PHARMACEUTICAL  
COMPOSITIONS AND METHODS FOR PREVENTING  
FOOD-DRUG INTERACTION

INFORMATION DISCLOSURE STATEMENT  
(SUBMISSION AFTER FILING OF AN APPLICATION  
BUT BEFORE FINAL REJECTION OR NOTICE OF ALLOWANCE  
OR CONCURRENTLY WITH A RULE 1.114 RCE APPLICATION)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

June 24, 2004

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications, or other information submitted for consideration by the Office are listed on the PTO-1449(s), attached hereto.

II. COPIES (check at least one box)

- a. ☐ This application was filed before June 30, 2003. Accordingly, submitted herewith is a legible copy of (i) each U.S. and foreign patent; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed.
- b. ☒ This application was filed on or after June 30, 2003. Accordingly, copies of cited U.S. patents and patent application publications therefore are not included. Copies of foreign

patent documents and non-patent literature are included.

- c. ☐ Some or all of the documents listed on the PTO-1449 are not enclosed because they were cited in the International Search Report and copies should already be in the PTO file. If copies are needed, please contact the undersigned.

III. CONCISE EXPLANATION OF THE RELEVANCE  
(check at least one box)

- a. ☒ **DOCUMENTS IN THE ENGLISH LANGUAGE**

The patents, publications, or other information listed on the attached PTO 1449 are in the English language and therefore, do not require a statement of relevancy.

- b. ☐ **DOCUMENTS NOT IN THE ENGLISH LANGUAGE**

A concise explanation of the relevance of all patents, publications, or other information listed that is not in the English language is as follows:

- c. ☐ **ENGLISH LANGUAGE SEARCH REPORT**

An English language version of the search report or action that indicates the degree of relevance found by the foreign office is attached, thereby satisfying the requirement for a concise explanation. See MPEP 609(III) (A) (3).

- d. ☐ **OTHER**

The following additional information is provided for the Examiner's consideration.

FEES

IV. ☒ THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(b):  
(check one box)

- a. ☐ within three months of the filing date of a national application (37 C.F.R. § 1.97(b)(1)). No fee or statement is required. *(This section is not to be used with RCE's.)*
- b. ☐ within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or statement is required.
- c. ☐ concurrently with the filing of a Request for Continued Examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.
- d. ☒ before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or statement is required.  
In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the statement under 37 C.F.R. § 1.97(e) below, or, if no statement has been made, charge our deposit account in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).

V. ☐ THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(c):  
(check one box)

before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c)(1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c)(2)).

- a. ☐ No statement; therefore, a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).
- or
- b. ☐ See the statement below. No fee is required.

VI. STATEMENT UNDER 37 C.F.R. § 1.97(e) (check only one box)

The undersigned hereby states that

- a. ☐ each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than 30 days prior to the filing of this IDS; or
- b. ☐ each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
- c. ☐ no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the IDS.
- d. ☐ Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was first cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application and, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

VII. PAYMENT OF FEES (check one box)

- ☐ A check in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p) is enclosed for the above-identified fee.
- ☐ Please charge Deposit Account No. 02-2448 in the amount required by 37 C.F.R. § 1.17(p) for the above-indicated fee. A triplicate copy of this paper is attached.
- ☒ No fee is required.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule and charge the appropriate fee to Deposit Account No. 02-2448.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By   
James T. Eller, Jr., #39,538

P.O. Box 747  
Falls Church, VA 22040-0747  
(703) 205-8000

JTE:cms  
1599-0257P

Attachment(s): ☒ PTO-1449  
☒ Documents  
☐ Foreign Search Report  
☐ Fee  
☐ Other:

(Rev. 05/14/2004)



Form PTO-1449		ATTY. DOCKET NO. 1599-0257P		APPLICATION NO. 10/782,951					
<b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  (Use several sheets if necessary)				APPLICANT Ae-Ri KIM et al.					
				FILING DATE February 23, 2004					
		GROUP UNKNOWN							
<b>U.S. PATENT DOCUMENTS</b>									
EXAMINER INITIAL	DOCUMENT NUMBER	Kind	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE		
	US 5,294,615	A	1994-03-15	Meyer et al.					
	US 6,338,857	B1	2002-01-15	Seth					
	US 6,368,628	B1	2002-04-09	Seth					
	US								
	US								
	US								
	US								
<b>FOREIGN PATENT DOCUMENTS</b>									
	Office	DOCUMENT NUMBER	Kind	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION	
								YES	NO
<b>OTHER DOCUMENTS</b> (Include Name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.)									
	B.N. Singh, "Effects of food on clinical pharmacokinetics", Clinical Pharmacokinetics 1999, 37:3.								
	Lars E. Schmidt and Kim Dalhoff, "Food-Drug Interactions", Drugs 2002: 62(10), pp. 1481-1502.								
	Pao et al., "Reduced Systemic Availability of an Antiarrhythmic Drug, Bidisomide, with Meal Co-administration: Relationship with Region-Dependent Intestinal Absorption", Pharmaceutical Research, Vol. 15, No. 2, 1998, pp. 221-227.								
	V.S. Luciano, "The Digestion and Absorption of Food", Human Physiology, 5 <sup>th</sup> Ed., Ch. 16, pp. 526-545.								
	Vallez M-O et al., "Different food interaction for the orally active thrombin inhibitors S 18326 and S 31922 in dogs", XVIIth Congress of the International Society for Thrombosis and Haemostasis, Washington D.C., U.S.A., Poster 2289.								
	R.T. Shuman and P.D. Gesellchen, "Development of an Orally Active Tripeptide Arginal Thrombin Inhibitor", Pharmaceutical Biotechnology, Vol. 11, Integration of Pharmaceutical Discovery and Development, New York, 1998, pp. 57-80.								
	D. Gustafsson et al., "The Direct Thrombin Inhibitor Melagatran and Its Oral Prodrug H 376/95: Intestinal Absorption Properties, Biochemical and Pharmacodynamic Effects", Thrombosis Research, 101 (2001), pp. 171-181.								
EXAMINER					DATE CONSIDERED				
EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.									